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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,082	07/23/2001	Baldomero M. Olivera	2314-241	2448

6449 7590 07/29/2003

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EXAMINER

BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/29/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,082

Applicant(s)

OLIVERA ET AL.

Examiner

Gabriele E. BUGAISKY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 6-15 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group I, peptide M6.1 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that a particular class of conotoxins will share a conserved cysteine framework, disulfide bridging pattern and conserved molecular target. and that there is thus no serious search burden. This is not found persuasive because while it is agreed that that the μ - conotoxins share a general 3 dimensional structure and share a similar cysteine framework and disulfide bridging pattern, there indeed is a serious search burden. The Examiner is of necessity limited to the search tools at hand. No generic formula for ω -conotoxins has been presented. For search purposes, the Examiner does however, consider , a propeptide along with the mature protein, and, e.g., a modified Trp, to be the same as Trp. Applicant states that while the various conotoxins may be distinct from each other, there is no serious search burden and the scientific literature search While a general word search and search of the subclasses is performed, the Examiner disagrees with the Applicant's position, in that a search for the specific peptides must be made and that a computer search for more than a single specific peptide indeed constitutes a severe burden. The sequence databases are growing at an incredible rate, specific searches for each claimed sequences must be performed and the Examiner is not given unlimited search time and resources The search constitutes AT PRESENT a serious burden. The Examiner can only operate with the search tools currently available to her. The requirement is still deemed proper and is therefore made FINAL.

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Claims 3-4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The listing of references in the specification (pages 77-79) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or by Applicants on PTO-1449, they have not been considered.

Specification

Applicants are required under 37 C.F.R. 1.821-1.825 to amend their claims to specific sequences by citing the appropriate SEQ ID Nos. The amendments should reflect the amino acid numbers of the SEQ ID No.

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The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable code (e.g., page 1, line 30; page 5, line 29, etc.). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademark VYDAC has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claims 1-2 and 6-15 are objected to because of the following informalities: they read upon non-elected subject matter; . claims 1 and 5 recite Tables, not SEQ ID Nos.; and claim 6, line 4, recites the word “acceptable”. Claim 6 should presumably recite “acceptable”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-2 and 6-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for derivatives of SEQ ID NO:191 wherein a single amino acid is replaced, does not reasonably provide enablement for the full scope of derivatives which include substitutions at all amino acids.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. First, it must be pointed out the derivatives of M6.1 include non-elected subject matter, as the specification gives non-limiting examples of derivatives.. Second, no working examples of any derivatives have been provided. The claims include any derivatives, a large number of which may not be active as ω -conotoxin. Applicants have not taught to what extent one may change the primary structure and still allow the peptide to fold properly. A large number of derivatives would be expected to sterically hinder formation of the correct disulfide linkages and one has been given no tools to reasonably predict which (or how many amino acids) may be altered.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is noted that the generic sequence of the elected peptide (SEQ ID NO:191) does

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not contain Xaa1 or Xaa2 and the elected peptide SEQ ID NO: 375 contains no Xaas., thus this recitation is unclear with respect to the elected subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Olivera *et al.* (US 5587454 Cite #1 of paper #10). The patent reveals numerous ω -conotoxins including the sequence of RVIA/SNX-182 (SEQ ID NO:5), and discusses their uses in treatment for pain, schizophrenia, inflammation and epilepsy. This disclosed conotoxins may be considered derivatives of instant SEQ ID NO:191.

Conclusion

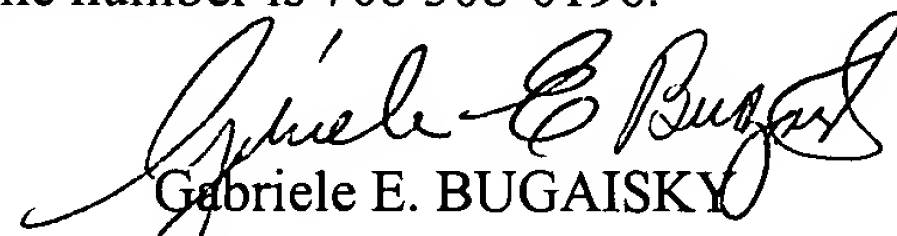
No claims are allowed. M6.1 conotoxin and its precursor peptide are deemed free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.


Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1653

July 27, 2003